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| APPLICATION NO | FILED DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO | CONFIRMATION NO |
|----------------|------------|----------------------|--------------------|-----------------|
| 09 696,929 | 10 25 2000 | Lee A. Bulla JR. | 48279-5USPT | 4758 |

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[REDACTED] EXAMINER

PRATS, FRANCISCO CHANDLER

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1651

DATE MAILED: 04 15 2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | | |
|-------------------|-----------------|--------------|
| | Application No. | Applicant(s) |
| | 09/696,929 | BULLA ET AL. |
| Examiner | Art Unit | |
| Francisco C Prats | 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 23 January 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 47-50,53,54,57 and 58 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 47-50 is/are rejected.

7) Claim(s) 53,54,57 and 58 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed January 28, 2003, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 51, 52, 55 and 56 have been cancelled.

Claims 47-50, 53, 54, 57 and 58 are pending and are examined on the merits.

Claim Rejections - 35 USC § 112

Claims 47-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As amended, claims 47-50 now recite the inhibition of any and all gram negative bacteria that excrete a mucoid exopolysaccharide. However, the specification as filed does not provide support for such language. There is nothing in the specification as filed which would indicate that the inhibition process should be applied only to gram negative bacteria, to the exclusion of other bacteria. This is a new matter rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 47-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Bochner et al (U.S. Pat. 6,046,020).

Bochner discloses the use of ibuprofen in the inhibition of capsule formation by gram negative bacteria. See, e.g., column 6, lines 29-36. A holding of anticipation is clearly required.

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Claims 47-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Chung et al (Current Microbiology 35:195-200 (1997)).

Chung discloses methods of assaying arylamine N-acetyltransferase activity, whereby intact cells of *Klebsiella pneumoniae*, a gram negative mucopolysaccharide producer, are contacted with ibuprofen. See, e.g., abstract, discussing inhibition of enzyme "in vivo." Because the claimed bacteria were contacted with the claimed inhibiting agent, growth, development and biofilm production must necessarily, i.e. inherently, have been inhibited. A holding of anticipation is clearly required.

Claims 47 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Demerson et al (U.S. Pat. 3,974,179).

Demerson discloses the inhibition of growth *Proteus vulgaris*, *Klebsiella pneumoniae* and *Serratia marcescens* by contacting those gram negative bacteria with indole derivatives of propionic acid present in growth medium. Note that the limitation requiring biofilm inhibition is considered to be met, based on the fact that the reference contacts the claimed organism with the claimed substance, the result thereof being inherent in performing the claimed process. A holding of

anticipation over the cited claims is clearly required. Lastly applicant is also reminded that propionates, i.e. compounds having a "propionic acid backbone" as recited in the claims, are notoriously well known preservatives.

Claims 53, 54, 57 and 58 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. In this regard, note that the amendment of January 28, 2003, did not amend these claims to contain all of the limitations of the base claims and any intervening claims.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS

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of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Francisco C Prats
Primary Examiner
Art Unit 1651

FCP
April 14, 2003